

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of
Bradford C. Webb
Serial No.: 08/055822
Filed: April 4, 1993
For: Synthetic Viscoelastic
Material for Ophthalmic
Applications

Declaration of Richard G. Livernois
Submitted Under 37 CFR 1.132

Honorable Commissioner of
Patents and Trademarks
Washington, D.C. 20231

Sir:

I, Richard G. Livernois, M.D., F.A.C.S., declare that:

1. I am a physician with 17 years of experience specializing in ophthalmology.
2. I obtained a Medical Doctor degree from Brown University in 1976.
3. I performed a residency in ophthalmology from 1977 to 1980 at the University of Pennsylvania.
4. I have published three articles discussing various aspects of ophthalmic surgery within the last ten years in nationally recognized ophthalmic journals.

5. I have taught numerous courses on cataract surgical techniques to other ophthalmologists since 1980.

6. I have performed over 4,000 cataract procedures during my career.

7. I am familiar with a range of viscoelastic materials, including cellulosic based materials, designed to be used during ophthalmic surgery.

8. I am familiar with the material marketed under the name of "Cellugel™" materials. This material was supplied to me by Dr. Brad Webb of Vision Biology, Inc. with the understanding this is the material claimed in United States Patent Application 08/055,822 filed April 4, 1994.

9. When using artificial cellulosic based materials other than Cellugel™ materials, I have often been hampered in surgery by the low static viscosity of these materials. Such materials do not provide sufficient viscosity to insure adequate anterior chamber volume, and are therefore not useful in providing the necessary protection required during modern cataract surgery procedures.

10. Another problem I have encountered with other cellulosic materials used for the same purpose is that they are sometimes fairly cloudy. This cloudiness makes it difficult to visualize the surgical site. It is my understanding that this cloudiness is an inherent property of prior available materials caused

by particulates and bubbles inside the material. In my experience, Cellugel™ materials is always perfectly clear.

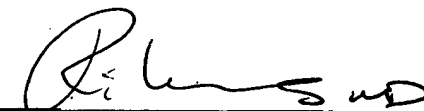
11. Another problem encountered with other cellulosic based materials is the occasional intraocular postoperative pressure created by impurities in these materials lodging in the trabecular meshwork. Unless corrective action is taken this high pressure may cause blindness. In my experience, I have never noticed a dangerously high postoperative intraocular pressure when I have used Cellugel™ materials during cataract surgery.

12. A further problem encountered with other cellulosic based materials, as well as all other FDA approved viscoelastic materials, including non-cellulosic viscoelastics sold in the United States, is that they are not sufficiently lubricous. A highly lubricous material has a greater ability to protect delicate tissues as surgical instruments and artificial lenses slide harmlessly over the tissue. The highly lubricous nature of Cellugel™ materials gives me confidence that the use of this material will prevent the tissues within the eye from contact damage. I have no knowledge of a viscoelastic material used for cataract procedures with the unique combination of high static viscosity, high lubricousness, high viscoelasticity and high clarity of Cellugel™ materials. I believe this innovative product is a significant improvement over cellulosic materials previously available.

DECLARATION

13. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that all statements were made with the knowledge that willful false statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both under 18 U.S.C. §1001 and that such willful false statements may jeopardize the validity of the application or any patent issuing thereupon.

Dated: March 10, 1994



Dr. Richard G. Livernois
for U.S. Patent Application
No. 08/055822